IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD. and ALLERGAN, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Senju Pharmaceutical Co., Ltd., ("Senju"), Kyorin Pharmaceutical Co., Ltd. ("Kyorin") and Allergan, Inc. ("Allergan") (collectively "Plaintiffs") allege for their complaint against Apotex Inc. and Apotex Corp. (collectively "Defendants" or "Apotex") as follows:

Nature of the Action

1. This is an action for infringement of United States Patent No. 6,333,045 ("the '045 Patent"), the claims set forth on the '045 Patent reexamination certificate, and United States Patent No. 5,880,283 ("the '283 Patent") under 35 U.S.C. §271(e)(2).

The Parties

2. Plaintiff Senju is a corporation organized under the laws of Japan having a place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

3. Plaintiff Kyorin is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311 Japan.

4. Plaintiff Allergan is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California, 92612.

5. On information and belief, defendant Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

6. On information and belief, defendant Apotex Corp. offers for sale and sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

7. On information and belief, defendant Apotex, Inc. is a corporation organized under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

8. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

9. On information and belief, Apotex, Inc. is formulating and/or plans to formulate gatifloxacin ophthalmic solution to be marketed and sold in the United States by Apotex Corp. Plaintiffs reserve the right to amend the complaint to substitute a different party for Apotex Inc. and/or Apotex Corp. if, through discovery, Plaintiffs discover that a company other than Apotex, Inc. and/or Apotex Corp. is formulating and/or marketing and/or selling gatifloxacin ophthalmic solution.

10. On information and belief, the acts of Apotex Corp. complained of herein were done with the authorization of, with the cooperation, participation, and assistance of, and in part, for the benefit of Apotex, Inc.

Jurisdiction and Venue

11. This action arises under 35 U.S.C. Section 1, *et seq.* This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Apotex because of its continuous and systematic contacts with Delaware. On information and belief, Apotex directly or indirectly purposefully sells, markets, distributes, and manufactures, goods for sale in the United States and Delaware; derives substantial revenue from things used or consumed in Delaware, regularly does and solicits business in Delaware; has filed counterclaims in this Court in other actions purposefully availing itself of the rights and benefits of this Court; and has admitted and/or consented to jurisdiction in this Court on numerous occasions, including with respect to another litigation involving gatifloxacin ophthalmic solutions versus the same Plaintiffs, *e.g., Senju Pharmaceuticals Co., Ltd et al.* v. *Apotex Inc. et al.,* 07-779 (D. Del.).

13. Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b).

Background

14. The '045 Patent, entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin," issued on December 25, 2001. A copy of the '045 Patent, reexamination certificate, and certificate of correction is attached to this complaint as Exhibit A.

15. Senju and Kyorin jointly own the entire right and interest in the '045 Patent.

16. Allergan is the exclusive licensee of the '045 Patent for ophthalmic uses.

17. The '283 Patent, entitled "8-Alkoxyquinolonecarboxylic Acid Hydrate With Excellent Stability And Process For Producing The Same," issued on March 9, 1999. Claim 1 of the '283 Patent claims gatifloxacin sesquihydrate. A copy of the '283 Patent is attached to this complaint as Exhibit B.

18. Kyorin owns the entire right and interest in the '283 Patent.

19. Allergan is the exclusive licensee of the '283 Patent for ophthalmic uses.

20. Each claim of the '045 Patent, the '045 Patent reexamination certificate, and the '283 Patent has a statutory presumption of validity that exists at all stages of a proceeding.

21. The '045 Patent was previously asserted by Plaintiffs against Apotex Inc. and Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.).

22. On June 21, 2010, the United States District Court for the District of Delaware entered judgment that Claims 1-3 and 6-9 of the '045 Patent were invalid as obvious.

23. On November 3, 2010, the United States District Court for the District of Delaware reopened the record to take additional testimony with respect to claim 7 of the '045 Patent.

24. On December 20, 2011, the United States District Court for the District of Delaware entered judgment that Claim 7 of the '045 patent was invalid as obvious.

25. Plaintiffs are appealing the district court's judgment with respect to Claim 7 of the '045 Patent from the United States District Court for the District of Delaware to the United States Court of Appeals for the Federal Circuit.

26. On February 25, 2011, Senju and Kyorin filed a request for reexamination of Claims 1-3, 6, 8 and 9 of the '045 Patent with the United States Patent and Trademark Office. Plaintiffs did not request reexamination of Claims 4, 5 and 7. The request was granted on April 28, 2011, and assigned Reexamination Application Control No. 90/011509.

27. During the prosecution of Reexamination Application Control No. 90/011509, Plaintiffs submitted, for consideration by the United States Patent and Trademark Office, the prior art, other evidence, and arguments relied upon by the Court and Apotex Inc. and

Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.) and the Court's decision in that case. Plaintiffs further canceled claims 1-3 and 8-11, amended claim 6 and added claims 12-16.

28. On October 25, 2011, the United States Patent and Trademark Office issued a reexamination certificate for the '045 Patent, canceling claims 1-3 and 8-11, and issuing amended claim 6 and new claims 12-16 as patentable over the opinion, prior art, other evidence, and arguments from *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.). The United States Patent and Trademark Office informed Plaintiffs of the publication of the '045 patent reexamination certificate on October 27, 2011.

29. Allergan is the holder of approved New Drug Application ("NDA") No. 22-548 that covers Zymaxid®, a 0.5% ophthalmic solution of gatifloxacin.

30. In conjunction with NDA No. 22-548, Allergan has listed the '045 Patent, the '283 patent and other patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") maintained by the U.S. Food and Drug and Administration ("FDA"). Allergan also informed FDA of the issuance of the '045 Patent reexamination certificate. Listing patents in the Orange Book obligates drug companies seeking approval to market a generic version of listed drug before the expiration of a listed patent to provide notice to the owner of the listed patent(s) and to the NDA holder with certain exceptions which do not apply to this case.

31. On information and belief, Apotex filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5% with a Paragraph IV certification.

32. Upon information and belief, ANDA No. 203523 refers to, and relies upon, Allergan's NDA No. 22-548 and contains data that, according to Defendants, demonstrates

the bioequivalence of the Defendants' proposed ANDA product to Allergan's Zymaxid® which is the subject of NDA No. 22-548.

33. In a letter dated January 13, 2012, Apotex advised Plaintiffs that it had filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5% which is the subject of Allergan's NDA. Allergan received that letter on January 16, 2012.

34. The January 13, 2012 letter purports to advise Plaintiffs pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. §314.95 that Apotex's ANDA No. 203523 had been filed with a Paragraph IV certification to obtain approval to market a gatifloxacin ophthalmic solution 0.5% before the expiration of either the '045 Patent or U.S. Patent 5,880,283 (the '283 patent).

35. The January 13, 2012 letter does not state where the product of ANDA No. 203523 is to be manufactured and/or formulated.

36. Upon information and belief, Apotex manufactured and continues to manufacture, at least some, gatifloxacin sesquihydrate.

37. Upon information and belief, Apotex's gatifloxacin API contains at least some gatifloxacin sesquihydrate.

COUNT 1

Infringement of Claims 6-7, 12, and 14-16

38. Paragraphs 1-38 are incorporated herein as set forth above.

39. Apotex's submission of ANDA No. 203523 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution 0.5% in the United States before the expiration of the '045 Patent is an act of infringement of Claim 7 of the '045 Patent and Claims 6, 12 and 14-16 set forth on the '045 Patent reexamination certificate under 35 U.S.C. § 271(e)(2)(A).

40. Defendants are jointly and severally liable for infringement of those claims..

41. Apotex's participation in the submission of ANDA No. 203523 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, Defendants were aware of the existence of the '045 Patent and the '045 Patent reexamination certificate and were aware that the filing of ANDA No. 203523 and certification with respect to the '045 Patent and the '045 Patent reexamination certificate constituted infringement. This is an exceptional case.

COUNT 2

Infringement of Claim 1 of the '283 Patent

43. Paragraphs 1-43 are incorporated as set forth herein.

44. Apotex's submission of ANDA No. 203523 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution, 0.5% in the United States before the expiration of the '283 Patent was an act of infringement of Claim 1 under 35 U.S.C. 271(e)(2)(A) of the '283 Patent.

45. Defendants are jointly and severally liable for infringement of the '283 Patent.

46. Apotex's participation in the submission of ANDA No. 203523 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '283 Patent under 35 U.S.C. §271(e)(2)(A).

47. Upon information and belief, Defendants were aware of the existence of the '283 Patent and were aware that the filing of ANDA No. 203523 and certification with respect to the '283 Patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A permanent injunction restraining and enjoining Defendants, its officers, agents, servants, employees, licensees and representatives, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '045 Patent and the '045 Patent reexamination certificate for the full term thereof;

B. A preliminary injunction restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '045 Patent and the '045 patent reexamination certificate for the full term thereof until such time as the Court issues a final decision on the merits;

C. A permanent injunction restraining and enjoining Defendants, its officers, agents, servants, employees, licensees and representatives, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '283 Patent for the full term thereof;

D. A preliminary injunction restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '283 Patent for the full term thereof until such time as the Court issues a final decision on the merits;

E. An award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

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